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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,214	12/01/2003	Muraleedharan G. Nair	MSU 4.1-672	4443
21036	7590	01/04/2006		
MCLEOD & MOYNE, P.C. 2190 COMMONS PARKWAY OKEMOS, MI 48864			EXAMINER FLOOD, MICHELE C	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/725,214

Applicant(s)

NAIR ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 30, 2005 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 3-5 are under examination.

Claim Rejections - 35 USC § 102

Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Andersen et al. (N) and Shigeta et al. (O).

Applicant claims a method for the inhibition of proliferation of cancer cells which comprises providing the cells an effective amount of malvidin in order to inhibit the proliferation of the cells. Applicant further claims the method of claim 1, wherein the cells are in a mammal; and wherein the cells are in a mammal and the malvidin is fed orally to the mammal.

With regard to Andersen, Applicant's arguments have been fully considered. However, the rejection stands for the reasons set forth in the previous action and for the

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reasons set forth below. Applicant argues that Andersen fails to teach the instantly claimed invention because "This reference does not describe the use of malvidin *per se*, but rather R3 "derivatives" of malvidin which contain a 3-position group." Applicant further argues that Andersen does not show any use of the aglycone, malvidin, among the compounds disclosed. However, Applicant's arguments are not persuasive because Andersen teaches a method of inhibiting the proliferation of cancer cells comprising orally administering an effective amount of malvidin to cancer cells in mammals to inhibit the proliferation of the cells in mammals. Please note that the teachings of Andersen are directed not only to a method for inhibiting the proliferation of cancer cells comprising the oral administration of an effective amount of an anthocyanidin derivative of the illustrated general formula 1, but also the use of an anthocyanidin thereof to inhibit the proliferation of neoplastic cells in mammals comprising the oral administration of an effective amount of an anthocyanidin of the illustrated general formula 1. See patent Claims 1 and 14; and page 15, lines 21-25.

Shigeta teaches a method for the use of treating leukemia comprising the administration of an effective amount of malvidin to the cells. Shigeta further teaches that the oral administration of malvidin for the treatment of leukemia.

Each of the references of Andersen and Shigeta anticipates the claimed subject matter.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Seeger (U).

Applicant's claimed invention of Claim 1 was set forth above.

Seeger teaches a method for the inhibition of the proliferation of cancer cells comprising the administration of an effective amount of malvidin (syringidin) to live cancer cells.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al. (N).

Applicant's claimed invention of Claims 1 and 4-5 was set forth above. Applicant further claims the method of claim 1, wherein the cells are stomach or colon tumor cells.

The teachings of Andersen are set forth above. While Andersen does demonstrate the administration of an effective amount of a composition comprising a derivative of malvidin to inhibit the proliferation of colon tumor cells to a human in need thereof, Andersen does not expressly teach a method for the inhibition of proliferation of cancer cells in an human, which comprises providing the cells an effective amount of malvidin in order to inhibit the proliferation of the cells, and wherein the cells are stomach or colon tumor cells. However, it would have been obvious to one of ordinary skill in the art to employ the method for inhibiting the proliferation of cancer cells comprising providing the cells with an effective amount of the anthocyanidin taught by Andersen to provide the instantly claimed invention because at the time the invention

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was made Andersen taught that the administration of an anthocyanidin or a derivative thereof having the general illustrated formula 1, including, malvidin, was useful in the treatment of various neoplastic diseases, including stomach or colon tumor cells, as set forth in Table III, on page 10 bridging page 12. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to employ the method for inhibiting the proliferation of cancer cells comprising providing the cells with an effective amount of the anthocyanidin taught by Andersen to provide the instantly claimed invention because at the time the invention was made Andersen taught that the administration of an anthocyanidin or a derivative thereof having the general illustrated formula 1, was useful in the treatment of colon cancer. See Figure 15. Thus, the instantly claimed invention would have been no more than a matter of judicious selection to one of ordinary skill in the art to orally administer an effective amount of malvidin to a human in need thereof given that Andersen teaches that anthocyanidins having a general structure of formula 1 exert the beneficial functional effect for inhibiting the proliferation of cancer cells.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seeger (U) in view of Tsuda et al. (V).

The teachings of Seeger are set forth above. Seeger teaches the instantly claimed method except for wherein the cells are stomach tumor cells; wherein the cells are in a mammal; and wherein the claim-designated compounds are fed orally to a mammal. However, it would have been obvious to one of ordinary skill in the art to provide the instantly claimed method for the inhibition of cancer cells of the stomach or colon comprising the oral administration of an effective amount of the claim-designated compound to a mammal because at the time the invention was made Tsuda taught that the oral administration of an effective amount of an anthocyanidin, such as the malvidin taught by Seeger, to a mammal was absorbed and metabolized *in vivo*. On page 181, Column 2, lines 9-11, Tsuda also teaches that the anthocyanin, (C3G) and its metabolites were detected in the stomach and jejunum of animals that received cyanidin by oral administration. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of providing the instantly claimed method of treatment because Seeger taught the carcinostatic effect of malvidin comprising administering an effective of malvidin to human cancer cells; and, Tsuda suggested that the oral administration of effective amounts of anthocyanins to mammals in need thereof may provide a protective potency in reducing the risk of carcinogenesis. See "*Results and discussion*", on pages 181-182.

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed method of treatment are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
December 20, 2005